

REMARKS

Claims 1-50 are pending and stand rejected under 35 U.S.C. § 103. In view of the following remarks, Applicant submits that the claims are in condition for allowance.

Rejections Under 35 U.S.C. § 103(a)

The pending claims are variously rejected as allegedly obvious over U.S. Patent No. 6,248,063 (hereinafter "Barnhill") in view of various secondary references. In particular, claims 1-5, 13-26 and 48 stand rejected as allegedly obvious over Barnhill. (Office Action, paragraphs 2-18). Claims 27-31 stand rejected as allegedly obvious over Barnhill in view of U.S. Patent No. 6,246,745 (hereinafter "Bi"). (Office Action, paragraphs 19-25). Claims 6-12 stand rejected as allegedly obvious over Barnhill in view of U.S. Patent No. 5,335,260 (hereinafter "Arnold"). (Office Action, paragraphs 26-32). Claims 32-45 and 47 stand rejected as allegedly obvious U.S. Patent No. 5,917,877 (hereinafter "Chiabrera"). (Office Action, paragraphs 33-46). Finally, claims 46, 49 and 50 stand rejected as allegedly obvious over Chiabrera in view of Barnhill. (Office Action, paragraphs 47-53). In support of the rejections based on Barnhill, the Office Action states:

Barnhill et al. do not explicitly disclose a method wherein the data is comprised of digitized x-ray images and the quantitative analysis is based on receipt of the x-ray images. It would have been obvious to modify the method of Barnhill et al. such that it was configured to receive digitized x-ray images for quantitative analysis. One would have been motivated to make such a modification so that images could be compared with modeling image data to track the progress/state of a disease as taught by Barnhill et al. (col. 20, lines 3-28). Additionally, it would have been obvious to a practitioner in the radiation art to utilize digitized images for transmission, since digitized images can be compactly converted for electronic transmission via network and for retrieval and storage. (Office Action, paragraph 6).

With regard to Chiabrera, it is alleged that it would have been obvious to modify the apparatus of Chiabrera to incorporate a calibration phantom. (Office Action, paragraph 35).

Applicant traverses the rejections and supporting remarks.

The pending claims are patentable over the cited references because there is no teaching, suggestion or motivation within this reference to support the assertions made by the Examiner. Moreover, the references fail to provide the requisite expectation of success and fail to teach all

the limitations of the claims. Additionally, the claims are patentable because of secondary considerations of non-obviousness.

Prima Facie Obviousness Has Not Been Established

In order to establish a *prima facie* case of obviousness, the burden is on the Office to establish that the cited reference (1) provide the requisite motivation to arrive at the claimed subject matter; (2) teach all the limitations of the claims; and (3) provide a reasonable expectation of success. *See, e.g.*, MPEP 2144. The references must suggest the desirability of arriving at the claimed subject matter. (*See, e.g., Amgen, Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991) stating that "hindsight is not a justifiable basis on which to find that the ultimate achievement of long sought and difficult scientific goal was obvious" and *In re Laskowski*, 10 USPQ2d 1397, 1399 (Fed. Cir. 1989) stating that "the mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification.")

Moreover, that which is "inherent" in a reference, if not known at the time of the invention, cannot form the basis for rejecting the claimed invention as obvious under section 103. *See, e.g., In re Shetty*, 195 USPQ 753 (CCPA 1977). Thus,

"The inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." *In re Shetty, supra* quoting *In re Sporman*, 150 USPQ 449 (CCPA 1966).

Applying these rules to the pending case, Applicant submits that the Office has not established that the references teach all the limitations of the pending claims and, in addition, has not established that the references suggest the desirability of the claimed invention. Moreover, the Office has improperly relied on information not known at the time of invention in making this rejection.

The references do not, explicitly or implicitly, teach or suggest all the limitations of the claims

In asserting the rejection under 103(a), the Examiner has acknowledged that Barnhill does not explicitly disclose systems and methods relating to digitized x-ray images. Nonetheless, the Office maintains that the use of Barnhill's systems as applied to digitized x-ray images. (Office Action, paragraph 6). Similarly, although the Office admits that Chiabrera does not explicitly disclose a calibration phantom comprising a marker in an area of known density, it is alleged that modification of Chiabrera's calibration phantoms was obvious and routine optimization of Chiabrera's disclosure. (Office Action, paragraph 36).

With regard to the rejections based on Barnhill, Applicant notes that the claimed subject matter to which Barnhill is applied is not, as asserted by the Office, directed to the transfer of data as described in this reference. First and foremost, Barnhill is silent as to transmission or analysis of digitized x-ray images *per se* but, rather, refers only to digitized data values of biomarkers or demographic values. (col. 7, line 49; col. 12, lines 52-67; col. 16, lines 57-65; col. 24, line 61-65). Indeed, Barnhill is clear that data values refer to processed biomarker or demographic values only:

The preprocessing step includes preparation of input values to be used as actual input to neural network based classifiers. This steps includes linear or non-linear transformation (e.g. re-scaling) of original input biomarker or demographic values which may be digitized values and/or the creation of secondary inputs using linear or non-linear combination of original input values. (Barnhill, col. 24, lines 58-65).

In other words, the only digitized data Barnhill suggests using are values obtained from biomarkers and/or demographic values. (See, Examples of Barnhill). X-rays are clearly not considered patient data in Barnhill's systems. X-rays are mentioned only in relation to "mechanistic modeling" (col. 20), namely comparison of digitized biomarker values with **known** information about particular diseases gathered from known diagnostic methods such as x-rays:

In this block, **available** knowledge and information about a particular disease process are used to establish mechanistic (realistic) models of some of the normal processes (physiological, anatomical, pharmacological, pathological, molecular biological, genetic, etc.) that are relevant to the origination of measured patient data... (Barnhill, col. 20, lines 3-10, emphasis added).

In sum, there is nothing in Barnhill that relates to the providing, transmitting and/or analysis of a digitized x-ray image itself. At best, Barnhill suggests that known and available information from x-ray images can be used as comparisons with other patient data values. This is a far cry from suggesting the methods as claimed.

Likewise, with regard to the assembly claims, Chiabrera suggests nothing in regard to placement of the calibration phantom in an area of known density, as claimed by Applicant. In this regard, recognizing the value of using a calibration phantom is worlds away from recognizing that tissues projecting with the calibration phantom could affect its apparent density. Chiabrera is focused on the materials making up the calibration phantom and assumes that

placement alongside the bone is sufficient to ensure accuracy. (Chiabrera, col. 6, lines 41-44 and claims). In contrast, Applicant's disclosure is directed to assemblies in which the position of the calibration phantom is taken into account in order to improve accuracy. (See, also, page 31, lines 14-27 of the application). Thus, Chiabrera does not teach or suggest all the limitations of the claimed assemblies.

When Applicant's claims and Barnhill and Chiabrera's teachings are properly evaluated and interpreted, it is clear that these references do not explicitly or implicitly suggest the claimed subject matter. As noted above, the law is well-settled that inherency cannot form the basis of an obviousness rejection. *See, e.g., In re Shetty*, 195 USPQ 753 (CCPA 1977). Therefore, the proposed modifications of Barnhill and/or Chiabrera do not fall within the spirit of their respective disclosures. Nowhere do the primary references report on the transmission and analysis of digitized x-ray images themselves or on the x-ray assemblies having precisely positioned calibration phantoms, as claimed. Accordingly, the primary references fail to teach or suggest all the limitations of the pending claims.

The secondary references do not in any way supply what is missing from the primary references. Arnold is directed to calibration phantoms and teaches nothing in regards to transmission of analysis of x-ray images, as set forth in claims 6-12 (to which this reference is applied in combination with Barnhill). Similarly, Bi is directed to devices and methods for receiving and processing digital images. (See, Bi, Abstract). Bi is silent in regard to transmission of x-ray images, as set forth in claims 27-31. The secondary references fail to teach the elements of the pending claims that are missing from the primary references and, moreover, fail to provide the motivation to arrive at the claimed invention (or suggest its desirability).

In sum, the fact remains that the claimed methods and assemblies were unknown prior to Applicant's disclosure and, on this basis alone, an obvious rejection is improper.

The references do not provide the requisite motivation to arrive at the claimed subject matter

The obviousness rejection is also improper because there is no motivation in any of the references to arrive at the claimed invention. The Office cannot simply state that the general level of skill in the art was high and, accordingly, the motivation is present. *See, e.g., In re Rouffet*, 47 USPQ2d 1453 (Fed. Cir. 1998) noting that the Office cannot rely on a high level of skill in the art to overcome the differences between the selected elements in the references, it cannot rely on a high level of skill in the art to provide the necessary motivation. Similarly, in *In re Lee*, 61 USPQ2d 1430 (Fed. Cir. 2002), the Federal Circuit affirmed that common knowledge and common sense are not the specialized knowledge and expertise necessary to establish a motivation to arrive at the claimed invention.

As noted above, Barnhill fails to disclose transmission and/or analysis of images. In addition, Barnhill fails to recognize that x-ray images (not data) can be digitized for transmission. Chiabrera fails to disclose that the soft tissue or other underlying structures can affect the apparent density of a calibration phantom. In other words, this is **not** an instance in which a skilled artisan would read Barnhill or Chiabrera and think for even one moment that the "patient data" in Barnhill includes an x-ray image transmitted to a remote computer and then analyzed or that the calibration phantoms in Chiabrera's assemblies should be positioned in an area of known density. Coupled with the fact that the Office has acknowledged that Barnhill and Chiabrera do not teach or suggest the limitations of the pending claims, it is clear that there was nothing routine about Applicant's disclosure that quantitative information could be derived from digitized and transmitted x-ray images and that placing calibration phantoms in areas of known densities provided superior results.

Briefly stated, the Office's assertion that the claimed subject matter is merely an obvious design choice in view of Barnhill or Chiabrera is untenable. The motivation to arrive at the claimed methods and assemblies is nowhere to be found in Barnhill or Chiabrera and the references themselves do not purport to have transmitted and analyzed x-ray images or to have placed the calibration phantom in an area of known density. The evidence of record clearly establishes that Barnhill and Chiabrera do not provide the requisite motivation to arrive at the claimed subject matter and that no combination of references teaches or suggests all the limitations of the claims. Accordingly, the Office has not met its burden regarding the first and second criteria needed to establish a *prima facie* case of obviousness.

The references do not provide a reasonable expectation of success

Turning now to the third and last criteria needed to establish a case of obviousness, Applicant notes that it is well settled that both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure. *In re Dow Chem.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Further, an Examiner cannot base an obviousness rejection on something that would have been "obvious to try" where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. *In re O'Farrell*, 7 USPQ2d 1673 (Fed. Cir. 1988).

In the case at hand, Applicant's claims are directed to (1) methods of transmitting x-ray images to a remote computer for analysis and (2) placement of the calibration phantom in an area of known density improves accuracy. For the reasons detailed above, Barnhill and Chiabrera fail to suggest such methods and assemblies. In the absence of these teachings, there could have been **no** expectation that the claimed methods and assemblies would have been successful. Accordingly, this rejection must be based, at best, on the "obvious to try" standard. This is not a

permissible basis for finding a reasonable expectation of success and cannot be used to support an obviousness rejection.

In sum, a *prima facie* case of obviousness has not been and, indeed cannot be, established. The properties of the claimed methods and assemblies are precisely defined - in the claims themselves, not in the art. To somehow conclude that Barnhill or Chiabrera teach or suggest these properties involves, at the very least, impermissible hindsight construction. Accordingly, Applicant respectfully requests that the rejection based on § 103(a) be withdrawn.

Additional Evidence of Non-Obviousness

Since no *prima facie* case has been established, Applicant has no burden of coming forward with evidence positively establishing nonobviousness. See, e.g., *In re Rinehart*, 189 USPQ 143 (CCPA 1976). Nonetheless, additional evidence is in fact of record in the present case, and that additional evidence further supports the nonobviousness of the presently claimed methods and assemblies. For example, it is clear from the application as filed that the ability to transmit and analyze digitized x-ray images and to provide assemblies in which the calibration phantom is positioned at a position of known gray value offered significant advantages over other image analysis systems and x-ray assemblies:

Advantages of the present invention include, but are not limited to, (i) providing fast, centralized networks for the analysis of x-ray images, particularly analysis of x-rays for bone mineral density; (ii) providing accessible and reliable means for analyzing x-rays; (iii) providing accurate calibration phantoms; (iv) providing accurate calibration phantoms that can be readily used with standard x-ray technology; and (v) providing methods and materials for making these network-enabled techniques and devices. (page 11, lines 18-23 of the application).

It is also abundantly clear from the application that the present invention solves problems that Barnhill and Chiabrera had failed to solve. (See, e.g., page 1, lines 17-29 noting that information obtained after transmission of digitized x-rays was not considered accurate; and page 1, lines 25-29, noting that placement of calibration phantoms was not considered prior to Applicant's disclosure). Thus, although a *prima facie* case of obviousness has not been made out (and indeed the reference contains no supporting basis), additional factual evidence of record in the present case lends further support to the nonobviousness of the claimed subject matter.

For the foregoing reasons, a *prima facie* case of obviousness has not been established. No combination of the cited references suggests the claimed methods and assemblies and,

additionally, provides the requisite reasonable expectation of success. Applicant urges the Office to withdraw the remaining rejection based on § 103(a).

CONCLUSION

Applicant submits that the claims are in condition for allowance and request early notification to that effect. If the Examiner has any further issues or wishes to discuss any of the foregoing, she is invited to contact Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

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By: Dahna S. Pasternak
Dahna S. Pasternak
Attorney for Applicant
Registration No. 41,411

Cooley Godward LLP
Five Palo Alto Square
3000 El Camino Real
Palo Alto, CA 94306
Tel.: (650) 843-5608
Fax: (650) 857-0663